

In the Title

Kindly replace the Title with the following:

**DEVICES ~~TO THAT~~ MONITOR ~~THE~~ PENETRATION OF AN INSTRUMENT IN AN
ANATOMICAL STRUCTURE**

In the Specification

Kindly replace paragraphs [0001] through [0047] with the following:

Related Application

This is a §371 of International Application No. PCT/FR2005/000340, with an international filing date of February 11, 2005 (WO 2005/077283 A1, published August 25, 2005), which is based on French Patent Application No. 04/01362, filed February 11, 2004.

Technical Field

~~The present invention concerns the domain of~~This disclosure relates to spinal surgery, and more particularly, the monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

Background

~~The prior art is already familiar with devices~~Devices used to follow the penetration of an instrument in an anatomical structure, in particular, a bone structure are known.

~~We are aware of European patent EP0607688 describing~~EP 0 607 688 describes a procedure and a system for the insertion of a pedicular vertebral screw, ~~consisting of~~including applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

~~We are also aware of a solution consisting of measuring~~It is also known to measure the modification in the impedance of the region ~~neighbouring~~neighboring the explored bone cavity~~[,]~~ using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to detect the gaps in bone matter, for example, during an operation preparing for the insertion of a pedicular screw in a vertebra.

The information gathered with such an solution approach is difficult to interpret[[],] since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

In addition, the device proposed is not very practical since it first requires a calibration (reference related to soft tissue). Finally, such a device remains not very easy to manipulate due to the presence of external cables.

The purpose of the invention is to correct these disadvantages by proposing an improved It could therefore be advantageous to provide a device[[],] whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

The present invention also aims at proposing an autonomous device, not requiring external cabling.

The present invention also aims at proposing a device offering improved and safer drilling conditions by informing the operator of the formation of gaps.

Summary

This invention relates to a device to monitor penetration of an instrument in an anatomical structure including at least two electrodes, a source of current supplying the at least two electrodes, and means for measuring impedance between the electrodes, wherein the electrodes are located on the penetration instrument, wherein the first electrode has a contact surface coinciding with a distal surface of the penetration instrument and the second electrode has a contact surface coinciding with a lateral surface of the penetration instrument, and wherein the contact surfaces are dimensioned to

have a coinciding and constant contact surface as a function of a degree of penetration of the penetration instrument in the anatomical structure.

Brief Description of the Drawings

Selected, representative aspects of the devices will be better understood upon reading the following description, referring to the appended figures where:

Figs. 1A and 1B, respectively, are a front sectional view and a longitudinal sectional view of a drilling instrument forming an exploration device;

Fig. 2 is a front sectional view of a drilling instrument;

Fig. 3 is a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

Fig. 4 is a longitudinal sectional view of a drilling instrument;

Fig. 5 is a perspective view of a drilling instrument;

Fig. 6 is a longitudinal sectional view of a penetration instrument comprising a tap; and

Fig. 7 is a longitudinal sectional view of a penetration instrument of a drilling instrument.

Detailed Description

~~For this purpose, according to its most general acceptation, the invention concerns a~~ We disclose devices to monitor the penetration of an instrument in an anatomical structure, in particular, a bone structure, comprising a source of current supplying at least two electrodes located on the aforementioned instrument and a means to measure the impedance between the aforementioned electrodes, and it is remarkable in that the aforementioned. The electrodes are located on the aforementioned penetration instrument so as to present a coinciding and constant contact surface as a function of the degree of entry of the aforementioned penetration instrument in the aforementioned bone structure.

More precisely, the invariability of the contact surface of the electrodes during the entry of the ~~aforementioned~~ penetration instrument is obtained by the dimensions of the ~~aforementioned~~ surface with respect to the dimensions of the hole formed in the bone structure by the ~~aforementioned~~ penetration instrument, since the dimensions of the ~~aforementioned~~ contact surface should not exceed those of the hole formed by the ~~aforementioned~~ penetration instrument.

The term “contact surface” refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the ~~aforementioned~~ penetration instrument.

Preferably, the ~~aforementioned~~ device comprises an electrode coinciding with the distal surface of the ~~aforementioned~~ penetration instrument.

“Distal” surface refers to the surface of the distal end portion of the ~~aforementioned~~ penetration instrument.

~~According to a first variant of the invention, the ~~aforementioned~~ The device may comprise~~ two electrodes coinciding with the distal surface of the ~~aforementioned~~ penetration instrument, since the ~~aforementioned~~ electrodes are substantially coaxially placed and separated by ~~an~~ insulation.

~~According to one variant of the invention, the ~~aforementioned~~ The device may also comprise~~ two electrodes coinciding with the distal surface of the ~~aforementioned~~ penetration instrument~~[,]~~ since the ~~aforementioned~~ electrodes are symmetrically placed with respect to a longitudinal axis of the ~~aforementioned~~ penetration instrument.

~~According to another variant of the invention, the ~~aforementioned~~ The device may further comprise~~ a plurality of electrodes coinciding with the distal surface of the ~~aforementioned~~ penetration instrument.

~~According to an advantageous mode of implementation of the invention, the aforementioned~~ The device may comprise[[s]] at least one electrode presenting~~having~~ a contact surface laterally coinciding with the ~~mentioned~~ penetration instrument. Advantageously, the ~~mentioned~~ electrode at least presents ~~an~~ has a substantially annular contact surface. Advantageously, the ~~mentioned~~ device comprises at least two electrodes presenting~~having~~ an annular lateral contact surface.

Advantageously, the ~~mentioned~~ device may comprise[[s]] a main electrode coinciding with the distal surface of the ~~mentioned~~ penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

~~According to a preferred mode of implementation of the invention, the aforementioned~~ The device may also comprise[[s]] means of signalling producing a signal at the time of detection of a variation in the impedance by the ~~mentioned~~ means of measurement.

Advantageously, the signal produced ~~is~~ may be a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

Therefore, when the ~~mentioned~~ instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the ~~mentioned~~ instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

Advantageously, the ~~mentioned~~ device may comprise[[s]] a central channel for the passage of an additional instrument.

~~The invention will be better understood upon reading the following description, referring to the appended figures where:~~

- ~~figures 1A and 1B respectively illustrate a front section view and a longitudinal section view of a drilling instrument forming the exploration device of the invention;~~
- ~~figure 2 illustrates a front section view of a first variant of the drilling instrument;~~
- ~~figure 3 illustrates a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;~~
- ~~figure 4 illustrates a longitudinal section view of a second variant of the drilling instrument;~~
- ~~figure 5 illustrates a perspective view of a third variant of the drilling instrument;~~
- ~~figure 6 illustrates a longitudinal section view of a penetration instrument comprising a tap; and~~
- ~~figure 7 illustrates a longitudinal section view of the penetration instrument according to another variation of the drilling instrument.~~

The device according to the invention is a device to monitor the penetration of an instrument in the bone structures of a human or animal body, the aforementioned structures presenting having at least two different zones of electric impedance.

The aforementioned electrodes, located on the aforementioned penetration instrument (1), are configured to present have a contact surface that remains constant during the penetration of the aforementioned penetration instrument.

The aforementioned electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

Therefore, since the impedance of the pedicular tissue is strictly superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

The aforementioned device also comprises means ~~effor~~ signalling ~~producing~~ that produce a specific signal at the time of the detection, by impedometer, of a variation in impedance[[],] and, therefore, ~~the~~ penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The aforementioned means ~~effor~~ signalling ~~consist of the~~ ~~include~~ emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator[[-]] ~~or the like~~).

A preferred example of the operating principle of the signalling of the detection of a gap is described below (~~figure~~ and shown in Fig. 3[[]]).

In the following section, the penetration instrument ~~consists of~~ ~~includes~~ a drilling instrument (1). However, the configurations presented below are, of course, applicable to other penetration instruments (tapping, curettage, spatulage[[-]] ~~and the like~~).

~~Figures~~ Figs. 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the aforementioned exploration device according to the invention.

In this first configuration, the drilling instrument (1) has, at the distal end portion, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

Electrode (2) comprises[[],] in this example ~~of implementation~~, the positive pole of the aforementioned electronic device, electrode (3) the negative pole. ~~It is of course obvious that this~~ This is only an one example of implementation[[],] and that the professional one skilled in the art may create an electronic device whose positive pole will ~~consist of~~ include electrode (3) and negative pole of electrode (2) without going beyond the invention scope of this disclosure.

Each electrode (2, 3) is arranged ~~so as to~~ coincide with the distal surface of the aforementioned drilling instrument (1).

In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the ~~aforementioned~~ drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

During the penetration of the instrument (1) in the bone structure, a signal is given off by the ~~aforementioned~~ means ~~off~~ for signalling when a variation in the impedance measured between the ~~aforementioned~~ electrodes (2, 3) is detected by the impedometer, indicating the formation of a gap.

At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if he so ~~wishes~~desired, then modifies the path of the drilling instrument (1) ~~so as to~~ return to the bone cortex.

Figure 2 illustrates a second configuration of the drilling instrument (1) comprising the ~~aforementioned~~ exploration device.

In this second configuration, the penetration instrument (1) ~~presents~~has two electrodes (2, 3) of sensibly identical circular section at its the distal end. The ~~aforementioned~~ electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

Since the position of the ~~aforementioned~~ electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

Since the number and shape of the electrodes is here provided by way of example, it is understood that the ~~aforementioned~~ penetration instrument (1) may ~~present~~have a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the ~~aforementioned~~ instrument (1).

~~Figure, 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the aforementioned means of signalling as a function of the impedance measured between the electrodes.~~

According to one preferential mode of implementation of the invention, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear (see figures shown in Fig. 3[()]). Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The aforementioned means of signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

Kindly replace paragraphs [0050] through [0055] with the following:

In the same way, it is possible to create penetration instruments ~~presenting~~ having other functionalities.

In particular, the aforementioned drilling instrument (1) may advantageously comprise at least one electrode (7) coinciding with the lateral surface of the aforementioned drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling instrument (1) (figure Fig. 7). It will thereby ~~be~~ be possible, due to the configuration of the aforementioned drilling instrument (1), to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone cortex by means of electrodes (5, 6). For this purpose, the positioning of a lateral electrode ~~consisting of~~ comprising a rod going to the

distal end should be avoided. In fact, it ~~would~~ is believed to be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument ~~in order to~~ to form annular bands of contact coinciding with the surface of the drilling instrument (1) (~~figure~~ Fig. 4).

~~According to one variant of the invention, the~~ The electrodes ~~will~~ may be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes ~~will~~ enables the volumetric detection of the perforations (~~figure~~ Fig. 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

~~Figure~~ 6 also illustrates the implementation of a penetration instrument configured for tapping. Advantageously, the ~~aforementioned~~ instrument (1) comprises a distal end in the form of a point and the lateral wall ~~presents~~ ~~has~~ cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the ~~aforementioned~~ instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1), but also laterally with respect to the wall of the ~~aforementioned~~ instrument (1) and provoked by at least one of the cutting stops.

The ~~invention is~~ devices are described above by way of example. It is understood that the professional ~~alone skilled in the art~~ is able to create different variants of the invention without going beyond ~~departing from~~ the framework of the ~~patent~~ devices as defined in the appended claims.